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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/725,897	11/30/2000	Mindy D. Goldsborough	45858/55672	9257
21874	7590	10/31/2003	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 9169 BOSTON, MA 02209			SISSON, BRADLEY L	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 10/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/725,897		GOLDSBOROUGH ET AL.	
	Examiner		Art Unit	
	Bradley L. Sisson		1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 8-12 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>Notice to Comply</i> . |

DETAILED ACTION

Specification

1. The specification is objected to as documents have been improperly incorporated by reference. See page 10, lines 23-24; page 15, line 9; page 37, lines 9-10; page 50, lines 5-9; page 68, lines 13-14; page 69, lines 15-16; and page 105, lines 19-23. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

2. The disclosure is objected to because of the following informalities:

a. The specification has been found to contain multiple sets of examples, which are not numbered in one series. The following examples have been found:

- i. Example 1, pages 75-78
- ii. Example 2, pages 78-80

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- iii. Example 3, pages 80-81
- iv. Example 4, pages 81-82
- v. Example 5, pages 82-83
- vi. Example 6, page 84
- vii. Example 7, page 84
- viii. Example 8, page 85
- ix. Example 9, pages 85-86
- x. Example 10, pages 86-87
- xi. Example 11, page 87
- xii. Example 12, page 88
- xiii. Example 13, pages 88-89
- xiv. Example 1, pages 94-95
- xv. Example 2, page 95
- xvi. Example 3, pages 95-96
- xvii. Example 4, pages 96-102
- xviii. Example 5, pages 102-103.

b. The specification has been found to contain multiple Sequence Listings (see pages 50-51 and 105-108 of the marked-up version of the specification), while only one is permitted. The Sequence Listing found at page 105 does not correctly identify sequences labeled in the body of the specification. See, for example, SEQ ID NO: 1 at page 43, lines 14-15, of the marked-up version of the specification.

Appropriate correction is required.

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3. The amendment filed 11 March 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: That portion of the specification added to marked-up pages 20-89, 98-99, and 102.

4. Acknowledgement is made of where at page 3 of the Office in the Office action mailed 26 March 2002 the specification was objected to as essential subject matter had been incorporated by reference. While applicant has undertaken efforts to bring such subject matter into the present application, that material deemed essential to enabling the present application was not properly incorporated by reference, as the original specification did not “clearly indicate where that material is found in the various documents”. See *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679, *supra*.

5. Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Amendment

6. The amendment filed 11 March 2003 is objected to because it does not include a new Sequence Listing, a new Computer Readable form of said Sequence Listing, and a statement that “the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing” and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d). A statement that the sequence listing information is identical is required.

Claim Objections

7. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.
8. A claim, which depends from a dependent claim, should not be separated by any claim that does not also depend from said dependent claim. In the present case, claims 8-12 and 16 are separated from independent claim by claims 6 and 7, of which claim 6 is an independent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).
9. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 requires that the "solid medium" be a "matrix," however, the material recited in claim 11 effectively broadens the scope of claim 1 to where the "solid medium" is something other than a "matrix."
10. Applicant is advised that should claim 12 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a “written description of the invention” which is separate and distinct from the enablement requirement. The purpose of the “written description” requirement is broader than to merely explain how to “make and use”; the “applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.

13. As presented above, the specification has been found to be replete with new matter, and that the new matter added cannot be relied upon to support the written description requirement of 35 USC 112, first paragraph. A review of the remaining or not affected portions of the disclosure fails to provide an adequate written description of the claimed method of producing one or more cDNA molecules so as to reasonably suggest that applicant, at the time of filing, was in possession of the invention. Accordingly, and in the absence of convincing evidence to the contrary, claims 1-16 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

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14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. The term "weak" in claims 7 and 8 is a relative term that renders the claims indefinite. The term "weak" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

17. The term "substantially" in claim 6 is a relative term that renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

19. Claims 1, 2, 4, 10, 11, 12, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,759,820 (Hornes et al.).

20. Hornes et al., columns 6-8, disclose binding of mRNA to a solid support and then subjecting the isolated/immobilized mRNA to reverse transcriptase so to produce a corresponding cDNA. The aspect of synthesizing a double-stranded cDNA is also disclosed therein.

Response to argument

21. At pages 81-82 of the response of March 11, 2003, applicant asserts that the claimed method is not anticipated by the prior art of record, as “the mRNA of the claimed invention is not hybridized to probes, which are themselves attached to the solid medium or support. Rather, the mRNA is sorbed to the solid medium (e.g., as in claims 1, 2, and 4). The present invention does not require an insoluble support that includes magnetic particles, a coating comprising oligo-dA to reduce non-specific binding, or an attached oligonucleotide (e.g., oligo-dT).”

22. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. It is noted with particularity that the claimed method does not specify how the mRNA is sorbed to the solid medium. Accordingly, the claim has been interpreted as encompassing both direct and indirect sorption. Accordingly, indirect sorption is

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fairly interpreted as encompassing the sorption of mRNA to a probe that is in turn bound to the solid medium.

23. While agreement is reached in that the claimed method does “not require an insoluble support that includes magnetic particles, a coating comprising oligo-dA to reduce non-specific binding, or an attached oligonucleotide (e.g., oligo-dT),” the claims method also does not exclude same. Accordingly, the claimed method has been interpreted as fairly encompassing such embodiments. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. Claims 1-5, 10-12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Pharmacia Biotech Catalog (1994).

26. Pharmacia Biotech Catalog (1994), page 119, discloses for sale spin columns that are packed with oligo-dT cellulose and that these solid mediums are used in methods whereby mRNA is isolated and cDNA is subsequently produced therefrom. Said cDNA is disclosed as being used in amplification assays such as PCR.

27. The aspect of producing a library of cDNA is disclosed in the figure seen on page 119 where a range of cDNA sizes are produced from a variety of cellular sources.

Response to Arguments

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At pages 84-85 of the response received March 11, 2003, applicant reiterates the traversal placed against the use of Horne et al., in the above rejection. While agreement is reached in that the prior art does use a matrix solid (cellulose) medium that has bound to its surface oligo-dT binding moiety, the claimed method does not exclude such embodiments. Accordingly, the prior art is considered to fairly anticipate the claimed invention.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

29. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

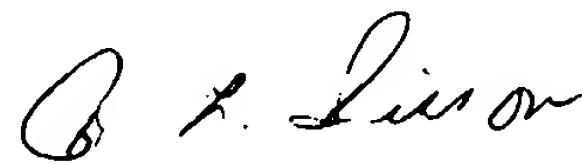
30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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31. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

32. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
October 29, 2003